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July 17, 2006

The Honorable Kent A. Jordan  
United States District Court for the District of Delaware  
844 King Street, Lockbox 10  
Wilmington, DE 19801

RE: Sepracor Inc. v. Dey, L.P. and Dey, Inc.,  
C.A. No. 06-113 (KAJ)

Dear Judge Jordan:

In response to the Court's June 22, 2006 Order (D.I. 15), the parties submitted their Joint Proposed Discovery Plan (D.I. 22) on July 14, 2006. Counsel for Plaintiff Sepracor Inc. ("Sepracor") and counsel for Defendants Dey, L.P. and Dey, Inc. (collectively "Dey") conferred on several occasions after receiving the Court's June 22 Order. While some progress was made, Sepracor and Dey continue to differ on how they expect this case to proceed. Thus, where agreement could not be reached, the parties presented each side's proposed calendar and sequence of events in the Joint Proposed Discovery Plan. I respectfully submit this letter to explain why Sepracor's proposed calendar and sequence of events differ from Dey's views.

This patent infringement action is the *second* Paragraph IV Hatch-Waxman Act litigation brought by Sepracor against a generic pharmaceutical company attempting to copy Sepracor's XOPENEX® (levalbuterol hydrochloride) inhalation solutions.<sup>1</sup> The first litigation, against a generic pharmaceutical company called Breath Limited, is currently pending in the District of Massachusetts. *Sepracor Inc. v. Breath Ltd.*, No. 06-10043-DPW (D. Mass.) (hereinafter, the "Massachusetts action"). The Massachusetts action involves all six of Sepracor's patents listed in FDA's Orange Book in connection with Sepracor's XOPENEX® (levalbuterol hydrochloride) inhalation solutions. This case against Dey involves five of the same six Sepracor patents.

Sepracor's view is that the dates and sequence of events in this case against Dey should be no sooner or different than those in the Massachusetts action. A copy of Judge Woodlock's Scheduling Order in the Massachusetts action is attached hereto as Appendix A. For this reason, Sepracor proposed a discovery plan in D.I. 22 that tracks the Massachusetts action. Dey, on the

<sup>1</sup> The timing for filing suit by the innovator company, in this case Sepracor, is dependent upon notice by the generic company that it filed an Abbreviated New Drug Application ("ANDA") with a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii) (indicating that FDA approval shall be made unless a patent infringement action is brought "before the expiration of 45 days after the date on which notice . . . is received[.]")

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other hand, has proposed a discovery plan in D.I. 22 that would have most events occur sooner than they will occur in the Massachusetts action.

It is noted that this case against Dey was filed months after the Massachusetts action. Thus, when viewed in terms of overall pendency of the lawsuit, Sepracor's proposed discovery plan in this case moves to resolution more rapidly than the Massachusetts action. Nevertheless, Sepracor is very sensitive to this Court's calendar. By having concurrent and consistent discovery schedules between the two cases (both in timing and format), resources can be conserved by, for example, consolidating document production and witness depositions. This would not only reduce the burden on various party witnesses, but also reduce the burden on likely third party witnesses that would be deposed in both cases. Concurrent scheduling and consistent sequence of events (*e.g.*, keying the date for submission of summary judgment motions and briefs off of the date of a ruling on claim construction), with the Massachusetts action would also reduce the risk of potentially inconsistent claim construction determinations and duplicative summary judgment briefings. Therefore, such a schedule would conserve this Court's resources as well.

Moreover, Sepracor is fully cognizant of the parties statutory duty to "reasonably cooperate in expediting this action." 21 U.S.C. § 355(j)(5)(B)(iii). It is Sepracor's position that its proposal to track the schedule in the Massachusetts action fully complies with its statutory obligation in this case. As Judge Woodlock indicated with respect to the Scheduling Order in the Massachusetts action, "[t]his Order . . . insur[es] the effective, speedy and fair disposition of cases, either by settlement or trial." *See* Appendix A.

Additionally, Dey would not be prejudiced by Sepracor's proposed discovery plan. These Paragraph IV Hatch-Waxman Act litigations are unique because it is the submission of an ANDA with a Paragraph IV certification that constitutes the act of infringement. 35 U.S.C. § 271(e)(2)(A). Once a patent infringement action is brought, the generic company's ANDA can not be approved by FDA for a period of time that is dictated by 21 U.S.C. § 355(j)(5)(B). Since Dey is not the first generic company to submit an ANDA for Sepracor's XOPENEX® (levalbuterol hydrochloride) inhalation solutions with FDA that contains a Paragraph IV certification, the key period of time is 180 days after the first commercial marketing of the drug by the first applicant. 21 U.S.C. § 355(j)(5)(B)(iv). Commercial marketing by the first applicant in this instance is dependent on resolution of its patent infringement action. 21 U.S.C. § 355(j)(5)(B)(iii). Here, Dey can not obtain FDA approval or engage in commercial marketing of the drug until after resolution of the Massachusetts action.

Therefore, there is no sound basis for moving this case ahead in schedule before the Massachusetts action. Instead, in the interest of judicial economy, this case against Dey should not proceed faster than the Massachusetts action.

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We look forward to discussing the parties' views with the Court during the Rule 16 teleconference on Wednesday, July 19, 2006. In the meantime, if the Court has any questions I know that Dey's counsel and Sepracor's counsel would be pleased to respond.

Respectfully submitted,

/s/ Richard D. Kirk (rk0922)

RDK/ABS

Enclosure

cc: Clerk of Court, by hand

All counsel of record as shown on attached service list

## **APPENDIX A**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

SEPRACOR, INC  
Plaintiff

CIVIL ACTION NO. 06-10043-DPW

v.

BREATH LIMITED  
Defendant

SCHEDULING ORDER

WOODLOCK, D.J.

This Order is intended primarily to aid and assist counsel in scheduling and planning the preparation and presentation of cases, thereby insuring the effective, speedy and fair disposition of cases, either by settlement or trial.

The above-entitled action having been heard on March 30, 2006, it is hereby ORDERED pursuant to Rule 16(b) of the Federal Rules of Civil Procedure and Local Rule 16.1(F), that:

- (1) all trial experts are to be designated and disclosure of information contemplated by FRCP, Rule 26 provided by the party bearing the burden of proof no later than **MAY 25, 2007**, disclosure of rebuttal experts no later than **JULY 13, 2007**, and any supplement expert reports by **AUGUST 10, 2007**. Depositions of expert witnesses shall be completed by **OCTOBER 31, 2007**.
- (2) discovery is to be completed by **MARCH 23, 2007**, unless shortened or enlarged by Order of this Court;
- (3) **MARKMAN BRIEFS:** Briefs on claim constructions due by **DECEMBER 15, 2007**. Responsive briefs due by **JANUARY 19, 2008**. A MARKMAN Hearing is set for **FEBRUARY 21, 2008 AND FEBRUARY 22, 2008 from 9:00 am to 5:00 pm** in Courtroom 1 on the 3<sup>rd</sup> floor before Hon. Douglas P. Woodlock, U.S.D.J.
- (4) **ELECTRONIC FILING:** All future submissions in this case are subject to electronic filing and all counsel who choose to appear must make arrangements to register for participation in electronic case filing, if they have not already done so. In

addition to electronically filing any pleading, counsel shall also file all submissions relating to dispositive matters with the Court in hard copy, clearly marked "**Courtesy Copy - Do Not Scan**" on the cover page of each pleading/submission. Notices, orders and memoranda of the Court will only be filed and served electronically.

All provisions and deadlines contained in this order having been established with the participation of the parties to this case, any requests for modification must be presented to the judge or magistrate judge, if referred for case management proceedings. Any requests for extension will be granted only for good cause shown supported by affidavits, other evidentiary materials, or reference to pertinent portions of the record. The request shall be made by motion and shall contain the reasons for the request, a summary of the discovery which remains to be taken, and a date certain when the requesting party will complete the additional discovery, join other parties, amend the pleadings or file motions. The Court may then enter a final scheduling order, if necessary.

Counsel are encouraged to seek an early resolution of this matter. Additional case management conferences may be scheduled by the court or upon the request of counsel, if the Court can be of assistance in resolving preliminary issues or in settlement.

By the Court,

/s/ Michelle Rynne  
Deputy Clerk

DATED: May 3, 2006

**CERTIFICATE OF SERVICE**

The undersigned counsel certifies that, on July 17, 2006, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

Steven J. Balick, Esquire  
John G. Day, Esquire  
Tiffany Geyer Lydon, Esquire  
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222 Delaware Avenue, 17th Floor  
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The undersigned counsel further certifies that, on July 17, 2006, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

Edgar H. Haug, Esquire  
Kimberly J. McGraw, Esquire  
Frommer, Lawrence & Haug, LLP  
745 Fifth Avenue  
New York, NY 10151

/s/ Richard D. Kirk (rk0922)  
Richard D. Kirk